



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,633	02/05/2002	Yusuf Ali	GOJO.01211	8088
29668	7590	04/23/2007	EXAMINER	
Johnson & Johnson 201 TABOR ROAD MORRIS PLAINS, NJ 07950			KIM, VICKIE Y	
			ART UNIT	PAPER NUMBER
			1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/068,633	Applicant(s) ALI ET AL.	
	Examiner Vickie Kim	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,8,9,12 and 25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 8-9, 12 and 25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

RCE acknowledged

A request for continued examination(RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/7/2006 has been entered.

Status of Application

1. The petition request filed 6/7/06 for revival satisfied the provisions of 37 CFR 1.137(b) and thus, the petition is granted and the case is now subjected to be examined.
2. Acknowledgement is made of amendment filed 6/7/06. Upon entering the amendment, the claim 1 is amended and the claims 6-7 are canceled.
3. The claims 1, 3, 5, 8-9, 12 and 25 are pending and presented for the examination.

Response to Arguments

4. Applicant's arguments filed 6/7/2006 have been fully considered but they are not persuasive for the reasons as follows.

Specification Objection and Claim Rejections - 35 USC § 112(New Matter)

Art Unit: 1618

The 112 1st, new matter rejection (due to newly added portion without support from original disclosure) is withdrawn hereafter in view of amendment filed 6/7/06.

112 Rejections - 1st(Scope of Enablement)

The 112 1st, Scope of Enablement rejection is withdrawn hereafter in view of amendment filed 6/7/06.

132 Declaration and 102/103 rejection

Applicant filed 132 declaration and argument to overcome 102/103 rejections over McKenzie et al(US5976566) and Samour et al(US5976566). However, the argument or the declaration under 37 CFR 1.132 filed 6/7/2006 is insufficient to overcome the previously issued rejection based upon teachings and reasons as set forth in the last Office action. Summary of the reasons why the argument is not persuasive and why the claims are not patentably distinct over the prior art of the record are shown below.

First of all, applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

In his argument or declaration, applicant repeatedly alleges that the composition taught in prior art of the record is different from the instant claimed composition. However, applicant fails to distinguish how it is different. If the

unexpected results are achieved by instantly claimed invention, applicant should clearly states what component(s) which is(are) structurally different from prior art of the record is(are) responsible for producing different outcome. Since the claims are drawn to a composition, if there is(are) difference(s) such as unexpected result(clearness, different viscosity, etc) found in applicant's instantly claimed composition, the specific structural difference(patentably novelty) should be claimed. Since all the critical elements claimed are taught in the composition of prior art, the viscosity, or clearness, gel formationl,etc) should be considered to be inherent features which is naturally possessed by the composition having substantially same ingredients(claimed vs taught).

Furthermore, in response to applicant's argument regarding antimicrobial activity, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

For instance, both patentee's and applicant's composition require three critical elements, which are a lower C1-C4 alcohol(at least 60%), a carbomer(0.1-5%), and a sodium hydroxide(see claim 1). If the claimed composition has density of at least 0.8g.ml and has a viscosity of from about 1000 to 65000 centipoise at 70° F, the composition in patent should have same properties unless there is(are) materially different ingredient(s) or elements(s) is(are) responsible for different outcome(s). If there is(are) one, applicant should add the

Art Unit: 1618

ingredient(s) or element(s) into the instant claims to show the novelty of the claimed invention. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Thus, the rejection is maintained as shown in last office action and the claims are properly included in the rejection as before.

New rejections are now added due to new findings of pertinent prior arts. New ground of rejection is now prepared in addition to the rejection already issued previously.

112 Rejection, 2nd

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 8-9 recites the limitation "contains an amino acids(claim 8)" or "contains sodium hydroxide(claim 9)". However, there is insufficient antecedent basis for this limitation in the claim because claim 1 specifically limited to

Art Unit: 1618

a **neutralizer** selected from sodium hydroxide, potassium hydroxide, ammonium hydroxide, magnesium hydroxide or precursors thereof. Claim 1 uses a singular term where one particular neutralizer is limited to the list mentioned above, whereas the claims 8-9 use the plural term "contains" which open to more than possibly one neutralizer. Especially as to the claim 8, there is lack of antecedent basis for amino acids. Thus, the claims are being indefinite since the claims 8-9 implies more than one neutralizers being existed which can be broader than the scope defined by claim 1. One would not know what the metes and bounds of the claims are. To obviate this rejection, replacement of the term "contains" with "is" is suggested in claim 9. For the claim 8, it is suggested to replace the said term with "is" and to add "an amino acid selected from the group consisting arginine, cysteine and thiamine" back to claim 1.

Claim Objection

6. Claim 1 is objected to because of the following informalities: in lines 2-3, there is inadvertent typographical error was found. The phrase "from 1 to carbon atoms" has missing the numerical value "4" between "to" and "carbon atoms". Appropriate correction is required.

Claim Rejections - 35 USC § 102/103

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1618

3. Claims 1, 3, 5, 9, 12 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by, or alternatively, under U.S.C. 103(a) as being unpatentable over Samour et al(US 5,976,566).

Samour et al(US'566 hereinafter) teach a topical alcoholic gel 55-70% ethanol, isopropanol or mixture thereof, 0-2% of cellulosic thickener(e.g. carbopol® as a thickening agent, see col. 9, lines 1-7), a base to adjust the pH such as sod. Hydroxide to neutralize the formulation, see col. 3, lines 40-49 and see col. 4, lines 30-35.

As to viscosity and density of the claimed composition, US'566 teaches a specific viscosity in the range about from 1000 to 65000 centipose at 70 fahrenheit, the viscosity recited in preamble would have been inherently possessed by the composition taught by the patent because all the ingredients required by the claims are also included in the patented composition. One would have been readily envisaged that both patented composition and instant invention as claimed possess same physical properties(e.g. viscosity or density) because they comprises essentially same ingredients such as an aliphatic alcohols(C1-C4), a carbomer, and a neutralizer, absent evidence to the contrary.

All the critical elements required by the instant claims are well taught in the cited reference and thus, the claimed subject matter is not patentably distinct over the prior art of the record.

For any circumstances, same viscosity or density is not inherently possessed by composition taught by prior art of the record, it would have been still obvious to one of ordinary skill in the art at the time the invention was made to modify viscosity or density

Art Unit: 1618

to produce most stable and pharmaceutically or cosmetically appealing product and the technique and skills are well within skill level of the artisan having ordinary skill in the art and the modification are routinely practiced, and thus obvious, absent evidence to the contrary. See US 4970220, at col. 9, lines 30-35, extrinsic evidence for supporting this examiner's statement, for example, US'220 teaches, " The viscosity of carious personal care compositions may vary widely. However, for easy dispersing and enhanced stability it is generally preferred to employ compositions at viscosities from 2000 to 20,000 cps".

Such modifications are considered to be conventional and routine which commonly practiced in pharmaceutical/cosmetic industry and does not render the claims patentably distinct over the prior art of the record.

4. Claims 1, 3, 5, 9, 12 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by, or alternatively, under U.S.C. 103(a) as being unpatentable over Mckenzie et al(US 5747021).

Mckenzie et al(US '021, hereinafter) teach a transparent topical composition(e.g. gel) comprising alcohol such as isopropanol, a carbomer and sodium hydroxide(0.1%), see col.3, lines 5-14. Patent particularly teaches all the critical elements(i.e. 30-70% of isopropyl alcohol, 0.25-1.75% of carbomer), see claim 7.

As to claim 12, US'021 teaches glycerin or PEG-8 for "slip" effect which is referring to moisturizer or emollients in the field. Thus, one would have readily envisaged the claimed composition from Mckenzie(US'021)' teaching

Art Unit: 1618

As mentioned earlier in Samour's(US566, immediately above), the limitations (e.g. viscosity, density , antimicrobial activity) are inherently met by the composition taught in US'021 patent because all the essential elements required by the instant claims are substantially same. All the critical elements required by the instant claims are well taught in the cited reference and thus, the claimed subject matter is not patentably distinct over the prior art of the record.

In any event that the viscosity, or density is different than that of patented composition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify and employ claimed viscosity or density to produce in order to determine most attractive, effective and stable composition for the reasons set forth above in 102/103 rejection, and the technique and skills are conventionally known in routinely practice, absent evidence to the contrary, and thus obvious.

As to claim 3, US'021 teaches lower aliphatic alcohol and exemplifies isopropanol. Although it does not explicitly mention about ethanol, however, ethanol and isopropanol are particularly well known as functional equivalent species. The final product with ethanol or isopropanol (both are easily obtained at market place) is readily envisaged and the said substitution and such modifications are considered to be minor which does not render the claims patentably distinct over the prior art of the record.

5. Claims 1, 3, 5, 9, 12 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by, or alternatively, under U.S.C. 103(a) as being unpatentable over Blackman et al(US5013545) or (US5098717), individually.

Art Unit: 1618

US'545 teaches aqueous gel composition comprising 60-90 % ethyl alcohol, 0.1-3% of carbopols and 0.2-5% of a neutralizing agent such as sodium hydroxide or potassium hydroxide, see abstract and col. 3, lines 16-45. See abstract and col. 2 (lines 15-48) of US'717.

For the same reasons set forth above, the claims are properly included in this rejection.

6. Claims 1, 3, 5, 9, 12 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by, or alternatively, under U.S.C. 103(a) as being unpatentable over Ensminger et al (US4143141).

Examples 1-2 at col. 4-5, teaches ethyl alcohol (upto 80-99.9%), carbomer (0.1-2%) and sod. Hydroxide (q.s to make gel). For the same reasons above, the claims are properly included in this rejection.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samour (US'566); McKenzie (US'021); Blackman et al (US5013545) or (US5098717), Ensminger et al (US4143141), individually in view of BF Goodrich Tech. Disclosure ("neutralizing carbopol...", 1998).

The rejection is substantially same as one previously issued. Detailed rejection should be referred to one issued on 12/22/03.

Art Unit: 1618

Applicant's claim differs because it requires a specific neutralizer that contains an amino acid selected from the group consisting arginine, cysteine and thiamine.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to substitute sodium hydroxide with arginine containing neutralizer because BF Goodrich teaches that sodium hydroxide is functionally equivalent to arginine containing neutralizer, see figure 4. Thus, one would have been motivated to do so, with reasonable expectation of success because it is always desirable to have selection option to enhance the efficiency of the manufacturing process and reduce the manufacturing cost due to the convenience to obtain ingredients. The techniques and skills required for making such substitution is conventional knowledge or well within the skills of ordinary artisan as evidenced by the cited references.

Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01 (a).

Conclusion

1. No claim is allowed.
2. Modak et al(US6846846) is pertinent to the claimed invention.
3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579.

The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 1618

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**VICKIE KIM
PRIMARY EXAMINER**

Vickie Kim
April 14, 2007
Art unit 1618